

***United States Court of Appeals  
for the Second Circuit***



**APPENDIX**



ORIGINAL  
WITH PROOF  
OF SERVICE

# 75-6109

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## UNITED STATES COURT OF APPEALS

*for the*

### SECOND CIRCUIT

B  
P/S

ELIZABETH DALEY, M.D.,

Plaintiff-Appellant,

-against-

CASPAR W. WEINBERGER, Secretary of Health, Education and Welfare, ALEXANDER M. SCHMIDT, M.D., Commissioner of the Food and Drug Administration, CLIFFORD G. SHANE, Regional Director of the Food and Drug Administration, TERRY MUSSON, ALLEN R. HALPER, JOHN E. KLEMMER and THOMAS D. GARDINE, Employees of the Food and Drug Administration,

Defendants-Appellees.

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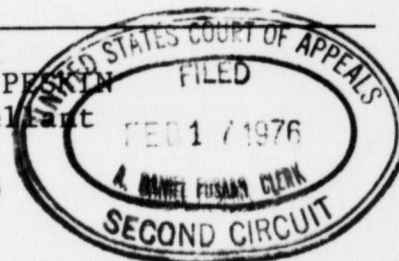
ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW YORK

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### APPENDIX

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ROTHBLATT, ROTHBLATT, SEIJAS & PERRY  
Attorneys for Plaintiff-Appellant  
232 West End Avenue  
New York, New York 10023  
(212) 787-7001



DAVID G. TRAGER, ESQ.  
United States Attorney for the  
Eastern District of New York  
Attorney for Defendants  
By CYRIL HYMAN ESQ.  
Assistant U.S. Attorney

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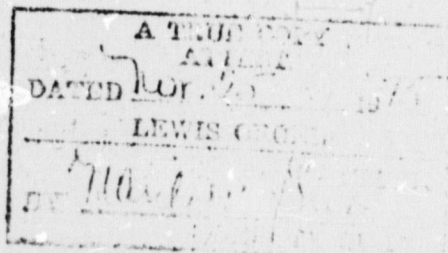
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75C 306

DALEY, et ano vs. WEINBERGER, et ano

DATE	NR.	PROCEEDINGS	
6-28-75		Complaint filed. Summons issued.	(1)
6-30-75		Unsigned order to show cause filed.	(2)
6-30-75		Memorandum of law in support of order to show cause filed.	(3)
6-30-75		Summons filed.	(4)
6-30-75		Amended complaint filed. Additional summons issued.	(5)
6-14-75		Additional summons returned and filed/executed.	(6)
6-17-75		Notice of motion dtd 5-14-75 for an order to dismiss etc filed with memorandum in support.	(7/8)
6-21-75		Notice to take deposition of the Arthritis Foundation, FIA of NY, George J. Gerstenberg filed.	(9)
6-27-75		Notice of motion dtd 6-4-75 re protective order filed with Memo of Law.	(10/11)
6-2-75		Memorandum of law in opposition to defts' motion for protective order filed.	(12)
6/5/75		Before NEAHER, J. - Case called- Attys for all sides present- Govt's motion argued and decision held in abeyance	
6-25-75		Supplemental memorandum in support of defts' motion to dismiss filed.	(13)
7-1-75		By NEAHER, J. - stipulation dtd 6-30-75 that plttf Henry Rosenberg be dismissed from this action filed.	(14)
7-3-75		Statement pursuant to Rule 9 (g) filed.	(15)
7-3-75		Notice to take oral deposition of Nicholas Falino filed.	(16)
7-9-75		Counterstatement pursuant to Local Rule 9 filed.	(17)
7-9-75		Memorandum in opposition to defts' motion to dismiss filed.	(18)
7/11/75		Before NEAHER, J. - Case called- Attys for both sides present- Deft's motion argued-Decision reserved.	
10-3-75		By NEAHER, J. Memorandum and Order dtd 10-2-75 granting defts' motion for summary judgment and directing the Clerk to enter judgment dismissing the complaint filed. (mg)	
10-6-75		JUDGMENT dtd 10-6-75 dismissing the complaint filed. (mg)	
10-31-75		Notice of appeal filed. Duplicate mailed to C of A.	
10/14/75		Stenographer's transcript of 7/11/75 filed.	



AMENDED COMPLAINT

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

ELIZABETH DALEY, M.D. and HENRY  
ROSENBERG, M.D.

Plaintiffs,

-against-

CASPAR W. WEINBERGER, Secretary of  
Health, Education and Welfare, ALEXANDER  
M. SCHMIDT, M.D., Commissioner of the  
Food and Drug Administration, CLIFFORD  
G. SHANE, Regional Director of the Food  
and Drug Administration, TERRY MUSSON,  
ALLEN R. HALPER, JOHN E. KLEMMER and  
THOMAS D. GARDINE, Employees of the Food  
and Drug Administration,

Defendants.

AMENDED COMPLAINT

75-C-306

Plaintiffs, by their attorneys, ROTHBLATT, ROTHBLATT, SEIJAS  
and PESKIN, allege as follows:

Jurisdiction

1. This action arises under the Fourth, Fifth and Sixth  
Amendments of the United States Constitution and the Federal Food,  
Drug and Cosmetic Act of 1938, 21 U.S.C. §§ 301, et seq., as here-  
inafter more fully appears. The matter in controversy exceeds, ex-  
clusive of interest and costs, the value of ten thousand dollars.

2. Jurisdiction of this Court is based upon 28 U.S.C. §§  
1331 and 1337.

3. This is an action for a preliminary injunction pursuant  
to Rule 65 of the Federal Rules of Civil Procedure, and a declara-  
tory judgment pursuant to 28 U.S.C. § 2201.

## AMENDED COMPLAINT

### Parties

4. Plaintiff ELIZABETH DALEY, M.D. is a physician duly licensed to practice medicine in the State of New York.

5. Plaintiff HENRY ROSENBERG, M.D. is a physician duly licensed to practice medicine in the State of New York.

6. Defendant CASPAR W. WEINBERGER is Secretary of the United States Department of Health, Education and Welfare.

7. Defendant ALEXANDER M. SCHMIDT, M.D., is Commissioner of the Food and Drug Administration of the United States Department of Health, Education and Welfare.

8. Defendant CLIFFORD G. SHANE is the Regional Director of the Food and Drug Administration.

9. Defendant TERRY MUSSON is an employee of the Food and Drug Administration.

10. Defendant ALLEN R. HALPER is an Investigator employed by the Food and Drug Administration.

11. Defendant JOHN E. KLEMMER is an Investigator employed by the Food and Drug Administration.

12. Defendant THOMAS D. GARDINE is an Investigator employed by the Food and Drug Administration.

### Plaintiffs' Medical Practice

13. Plaintiffs DALEY AND ROSENBERG are engaged in the practice of medicine in the State of New York and maintain offices for this purpose at 320 West End Avenue, New York City, New York.

AMENDED COMPLAINT

14. In the course of their medical practice, plaintiffs DALEY and ROSENBERG prescribe various medications, vitamins and diets for their patients in the treatment of rheumatoid arthritis and other rheumatic diseases. These medications include the drugs "prednisone," "testosterone," "estradiol," and combinations thereof.

15. Said drugs are all fully approved under applicable federal law for use in the professional practice of medicine.

16. The conduct of plaintiffs DALEY and ROSENBERG in preparing, prescribing and administering said drugs and combinations thereof to their patients is their lawful right and professional prerogative as duly licensed medical practitioners.

17. It is the professional judgment and opinion of plaintiffs DALEY and ROSENBERG that the administration of said drugs to their patients suffering from rheumatic diseases is indispensable to effective medical treatment, and that without the use of said drugs their patients' conditions would substantially deteriorate, resulting in increased pain, suffering and crippling to hundreds of individuals.

Defendants' Conduct

18. On or about February 10, 1975, defendant HALPER appeared at plaintiffs' offices at 320 West End Avenue, New York City, New York.

19. During said February 10, 1975 appearance at plaintiffs' offices, defendant HALPER interrogated Donna Pinorsky, R.N.

AMENDED COMPLAINT

about various aspects of plaintiff's medical practice and treatment of patients.

20. During said February 10, 1975 appearance at plaintiffs' offices, defendant HALPER did also serve upon Donna Pinorsky, R.N., a Notice of Inspection pursuant to Section 704 (a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 374 (a), a copy of which is annexed hereto and marked Exhibit "A."

21. On or about February 27, 1975, defendants KLEMMER and GARDINE appeared at plaintiffs' offices at 320 West End Avenue, New York City, New York.

22. During said February 27, 1975 appearance at plaintiffs' offices, defendants KLEMMER and GARDINE interrogated Donna Pinorsky, R.N.

23. During said February 27, 1975 appearance at plaintiffs' offices, defendants KLEMMER and GARDINE did also serve upon Donna Pinorsky, R.N., a Notice of Inspection pursuant to Section 704(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 374(a), a copy of which is annexed hereto and marked Exhibit "B."

24. Subsequent to February 10, 1975, and prior to February 27, 1975, plaintiffs' attorney, Henry B. Rothblatt, had telephone conversations with defendants KLEMMER and MUSSON concerning the purpose of the Notice of Inspection and the future intentions of the Food and Drug Administration with regard to plaintiffs DALEY and ROSENBERG.

AMENDED COMPLAINT

25. Upon information and belief, the Food and Drug Administration is conducting an investigation of plaintiffs' medical practice, and intends to continue said investigation, to include interrogation of plaintiffs as well entry and inspection of their offices at 320 West End Avenue, New York City, New York.

26. Upon information and belief, the claimed justification for the aforementioned investigation are alleged violations of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., concerning a "new drug" known as "Leifcort."

27. Plaintiffs have offered to fully disclose and openly discuss with appropriate Food and Drug Administration officials, through their attorney, all relevant details concerning the medications which they prepare, prescribe and administer to their patients. A copy of correspondence sent to the Food and Drug Administration to this effect is annexed hereto and marked Exhibit "C."

28. To date defendants have not availed themselves of the opportunity to resolve this matter through discussion with plaintiffs' attorney. As a result, the issue remains unresolved, and plaintiffs must continue to function under a constant threat of impending action against them by the Federal Government.

Defendants' Lack of Jurisdiction

29. As previously alleged herein, plaintiffs DALEY and ROSENBERG have the absolute right, as duly licensed physicians,

AMENDED COMPLAINT

to prepare, prescribe and administer approved drugs and combinations thereof to their own patients in the course of their medical practice.

30. The Federal Government, and specifically the Food and Drug Administration under the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., lacks jurisdiction and authority to investigate, inspect, or in any manner interfere with plaintiffs' medical practice and treatment of patients.

Injury

31. The conduct of the Food and Drug Administration, its officers and employees, in investigating, inspecting, threatening to do the same, or otherwise interfering with plaintiffs' right to practice medicine, is violative of the Fourth, Fifth and Sixth Amendments of the United States Constitution, the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., as well as the physician-patient privilege.

32. Said conduct of the Food and Drug Administration, its officers and employees, has caused and will continue to cause further irreparable injury to plaintiffs and their patients in that:

(a) Plaintiffs are being deprived of their right to be free from unreasonable search and seizure;

AMENDED COMPLAINT

(b) Plaintiffs are being deprived the right of effective assistance of counsel by defendants' refusal to discuss the matters in issue with plaintiffs' attorney;

(c) Defendants seek to prevent plaintiffs from lawfully practicing medicine in accordance with their own professional judgment and skill, in violation of the right to due process of law;

(d) Defendants seek to prevent plaintiffs from rendering effective medical treatment to their patients, which will result in increased pain, suffering and crippling of hundreds of individuals suffering from rheumatoid arthritis and other rheumatic diseases;

(e) Continued investigation by defendants will destroy plaintiffs' professional reputation, cause them to lose patients, and otherwise result in substantial permanent injury;

(f) Plaintiffs are being unlawfully subjected to possible criminal prosecution and resulting fine, imprisonment and loss of their licenses to practice medicine for refusal to permit an unauthorized inspection of their offices and/or other violations of the Food, Drug and Cosmetic Act, 21 U.S.C. § 331.

33. Said conduct of the Food and Drug Administration, its officers and employees, will continue unless permanently enjoined by this Court.

34. There is an actual controversy between the parties herein concerning defendants' authority and jurisdiction to in-

AMENDED COMPLAINT

investigate, inspect and otherwise interfere with plaintiffs' medical practice.

35. Plaintiffs have no adequate remedy at law.

WHEREFORE, plaintiffs respectfully request a judgment:

(a) Declaring that the Federal Government, and specifically the Food and Drug Administration of the Department of Health, Education and Welfare, lacks authority and jurisdiction to investigate, inspect or otherwise enforce the provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., against plaintiffs for their conduct in preparing, prescribing and administering approved drugs or combinations thereof to their own patients in the course of their medical practice.

(b) Enjoining and restraining defendants, their agents, employees, successors, and all other persons acting in their behalf, during the pendency of this litigation and thereafter permanently, from investigating, inspecting or otherwise enforcing the provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., against plaintiffs for their conduct in preparing, prescribing and administering approved drugs or combinations thereof to their own patients in the course of their medical practice;

(c) Awarding plaintiffs costs and such other and further relief as to this court seems just and proper.

AMENDED COMPLAINT

DATED: New York, New York  
March 3, 1975

Respectfully submitted,

ROTHBLATT, ROTHBLATT,  
SEIJAS & PESKIN  
Attorneys for Plaintiffs  
323 West End Avenue  
New York, New York 10023  
(212) 787-7001

AMENDED COMPLAINT

VERIFICATION

STATE OF NEW YORK )  
COUNTY OF NEW YORK) ss.:

HENRY ROSENBERG, M.D., being duly sworn, deposes and says that he is a plaintiff in the within action; that he has read the foregoing amended complaint and knows the contents thereof; that the same is true to his own knowledge except as to matters therein stated to be alleged on information and belief; and that as to those matters he believes it to be true.

*Henry Rosenberg, M.D.*  
HENRY ROSENBERG, M.D.

Sworn to before me this  
3 day of March 1975

*[Signature]*  
STEPHEN H. PEGION  
Notary Public, State of New York  
No. 0037460  
Qualified in New York County  
Commission Expires March 30, 1976

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS

350 3rd Avenue  
Brooklyn NY 11232

2. NAME AND TITLE OF INDIVIDUAL

James P. ... R.N.

3. DATE

2/10/75

4. FIRM NAME

Dr. Edward ...

ROOM

1110

a.m.

6. NUMBER AND STREET

320 1st E. Ave.

7. CITY AND STATE

New York, NY 10028

8. ZIP CODE

Notice of inspection is hereby given pursuant to Section 704(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)]<sup>1</sup> and/or Part F or G, Title III of the Public Health Service Act [42 USC 262-264].<sup>2</sup>

9. SIGNATURE (Food and Drug Administration Employee(s))

Albert H. ...

10. TITLE (Food and Drug Administration Employee(s))

Inspector

<sup>1</sup> Applicable portions of Section 704 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704. (a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j) or section 507 (d) or (g) of this Act, and data relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505 (j) of this Act). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

<sup>2</sup> Applicable sections of Parts F and G of Title III Public Health Service Act [42 USC 262 - 264] are quoted below:

Part F - Licensing - Biological Products and Clinical Laboratories and \*\*\*\*\*

Sec. 351(c) "Any officer, agent, or employee of the Department of Health, Education, and Welfare, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component

or derivative, allergenic product or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - \*\*\*\*\* Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs relate to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

Part G - Quarantine and Inspection.

Sec. 361(a) "The Surgeon General, with the approval of the Secretary is authorized to make and enforce such regulations as in his judgement are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgement may be necessary."

# AMENDED COMPLAINT

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS 850 THIRD AVE. BROOKLYN, N.Y. 11232	
2. NAME AND TITLE OF INDIVIDUAL James P. Hender R.N.		3. DATE 2-27-75	
4. FIRM NAME Mrs. Elizabeth Foley & Kathryn Recording		5. TIME 10:30 A.M.	
6. NUMBER AND STREET 320 West End Avenue		7. CITY AND STATE New York, N.Y.	
8. ZIP CODE 10023			

Notice of inspection is hereby given pursuant to Section 704(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)]<sup>1</sup> and/or Part F or G, Title III of the Public Health Service Act [42 USC 262-264].<sup>2</sup>

9. SIGNATURE (Food and Drug Administration Employee(s)) J. P. Hender	10. TITLE (Food and Drug Administration Employee(s)) INVESTIGATORS
---	---

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or derivative, allergenic product or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - \*\*\*\*\* Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (for testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

Part G - Quarantine and Inspection.

Sec. 361(a) "The Surgeon General, with the approval of the Secretary is authorized to make and enforce such regulations as in his judgement are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgement may be necessary."

AMENDED COMPLAINT

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ICS IPMMTZZ CSP  
1 2127877001 MGM TDMT NEW YORK NY 02-24 0946P EST  
ZIP 10023

**MAIL** Mailgram  
western union



△  
HENRY B ROTHBLATT  
232 WEST END AVE  
NEW YORK NY 10023

THIS MAILGRAM IS A CONFIRMATION COPY OF THE FOLLOWING MESSAGE:

2127877001 MGM TDMT NEW YORK NY 100 02-24 0946P EST  
ZIP

INSPECTOR JOHN KLENNER  
FOOD AND DRUG ADMINISTRATION  
850 3 AVE  
BROOKLYN NY 11232

WOULD YOU PLEASE INFORM ME THE BASES OF YOUR JURISDICTION TO  
INTERROGATE A MEDICAL DOCTOR SUCH AS DOCTOR DALEY CONCERNING HER  
MEDICATION AND PRESCRIPTION AND TREATMENT OF HER PATIENTS AS A DULY  
LICENSE PHYSICIAN. AS I TOLD YOU IN OUR TELEPHONE CONVERSATION I WILL  
BE PLEASED TO DISCUSS ALL ASPECT OF THESE MEDICATIONS WITH YOUR  
SUPERIORS AND ATTORNEYS

HENRY B ROTHBLATT ATTORNEY FOR DR ELIZABETH DALEY  
232 WEST END AVE  
NEW YORK NY 10023

21146 EST

MGMNY1T HSB

AFFIDAVIT OF ELIZABETH DALEY, M.D. IN  
SUPPORT OF TEMPORARY RESTRAINING  
ORDER

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

-----

ELIZABETH DALEY, M.D. and HENRY  
ROSENBERG, M.D.,

Plaintiffs,

AFFIDAVIT

-against-

CASPAR W. WEINBERGER, Secretary of  
Health, Education and Welfare, and  
MAX L. SCHMIDT, Commissioner of the  
Food and Drug Administration,

Defendants.

-----

State of New York )  
                          ) ss:  
County of New York)

ELIZABETH DALEY, M.D., being duly sworn, deposes and says:

I am a plaintiff in this action and a physician duly  
licensed to practice medicine in the State of New York. I main-  
tain my medical office at 320 West End Avenue, New York City,  
New York.

For several years my medical practice has concentrated  
on rheumatoid arthritis and other rheumatic diseases. The method  
of treatment which I employ is based upon special diet and the  
administration of various medications. These medications include  
the hormones prednisone, testosterone and estradiol which are  
administered in varying dosages according to the particular re-  
quirements of the individual patient. This method of treatment  
has proven to be successful with thousands of patients over a

AFFIDAVIT OF ELIZABETH DALEY, M.D. IN  
SUPPORT OF TEMPORARY RESTRAINING ORDER

period of many years.

I myself have a serious rheumatoid arthritis condition which is treated with these medications. It is because of this treatment that I am able to continue to function as an active medical practitioner.

On February 10, 1975 and February 27, 1975, Investigators from the Federal Food and Drug Administration came to my office, interrogated my nurse, Donna Pinorsky, R.N. and served Notices of Inspection. As a result of these incidents, and conversations with my attorney, Henry B. Rothblatt, I have learned that the Food and Drug Administration is conducting an investigation of my medical practice concerning alleged violations of the Food, Drug and Cosmetic Act.

Any medications which are prepared at my office are used solely in the treatment of my own patients as prescribed by me and my colleague, Dr. Henry Rosenberg. Further, any such medications are composed entirely of legally and medically approved drugs.

It is my understanding, and I again have recently been so advised by my attorney, that it is completely lawful for a licensed physician to prepare, prescribe and administer medications in the manner in which I have been so doing.

I cannot overemphasize the efficacy of the method of treatment which I employ. It is effective in treating rheumatic disease. To deny this medication and treatment to the thousands

AFFIDAVIT OF ELIZABETH DALEY, M.D. IN  
SUPPORT OF TEMPORARY RESTRAINING ORDER

of patients that are now using it successfully would result in needless suffering and crippling. This would be an outrageously inhumane act.

My medical practice cannot be conducted under a constant threat of unlawful intrusion by federal inspectors to say nothing of the harm to my professional reputation which results therefrom.

The present situation is intolerable and must be resolved as expeditiously as possible. It is for this reason that I urge the Court to prohibit the Food and Drug Administration from taking any further action in this matter pending final resolution of this controversy.

WHEREFORE, I respectfully request that the temporary restraining order and preliminary injunction sought herein be granted.

*Elizabeth Daley M.D.*  
ELIZABETH DALEY, M.D.

Sworn to before me this  
27<sup>th</sup> day of Feb. 1975

*Jon G. Rothblatt*  
JON G. ROTHBLATT  
Notary Public, State of New York  
No. 31-5577110  
Qualified in New York County  
Commission Expires March 22, 1976

MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

-----

ELIZABETH DALEY, M.D. and HENRY  
ROSENBERG, M.D.

Plaintiffs,

Civil No. 75-C-306

- against -

CASPAR W. WEINBERGER, Secretary of  
Health, Education, and Welfare, ALEXANDER  
M. SCHMIDT, M.D., Commissioner of the  
Food and Drug Administration, CLIFFORD  
G. SHANE, Regional Director of the Food  
and Drug Administration, TERRY MUSSON,  
ALLEN R. HALPER, JOHN E. KLEMMER, and  
THOMAS D. GARDINE, Employees of the Food  
and Drug Administration,

MOTION TO DISMISS  
AND FOR SUMMARY JUDGMENT

Defendants.

-----

I

Comes now the defendants, Caspar W. Weinberger, Secretary of Health, Education, and Welfare, Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, Clifford G. Shane, Regional Director of the Food and Drug Administration, Terry Musson, Supervisory Consumer Safety Officer, New York District, Food and Drug Administration, Allen R. Halper, John E. Klemmer, and Thomas D. Gardine, Consumer Safety Officers, New York District, Food and Drug Administration, Department of Health, Education, and Welfare by their attorneys, pursuant to Rule 12(b) and 56(b) of the Federal Rules of Civil Procedure, and moves the Court to dismiss the Complaint filed herein for a declaratory judgment that the federal government, and specifically the United States Food and Drug Administration, lacks authority and jurisdiction to investigate, inspect or otherwise enforce the provisions of the Federal Food, Drug, and Cosmetic Act, against plaintiffs and for an injunction restraining the defendants from investigating, inspecting or otherwise enforcing the provisions of the Federal Food, Drug, and Cosmetic Act, against plaintiffs; and the defendants alternatively move the Court to grant summary judgment of dismissal, for the following reasons and on the following grounds:

## MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

1. The Court is without jurisdiction to entertain the suit because it is in substance and effect a suit against the United States which has not consented to be sued or waived its immunity from suit.

2. The Complaint fails to state any claim upon which relief can be granted in that it presents no justifiable controversy. It seeks to enjoin the defendants in their official capacity from making investigations they are expressly authorized to make, pursuant to §§702(a) and 704 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 372(a) and 374], to determine whether the Act is being violated. Further, the relief demanded in the Complaint cannot be granted against Director Shane, Supervisory Consumer Safety Officer Terry Musson and Consumer Safety Officers Halper, Klenner, and Gardine who, as federal employees of subordinate rank, are subject to direction of their superiors.

3. The acts complained of, which the plaintiffs seek to have declared unauthorized by the Federal Food, Drug, and Cosmetic Act, and violative of the physician-patient privilege, and the Fourth, Fifth, and Sixth Amendments to the United States Constitution, are the attempts on two occasions by FDA investigators pursuant to 21 U.S.C. 374 to conduct an inspection of the premises where plaintiffs conduct a medical practice. The purpose of the two attempted inspections was to determine whether interstate shipments of a drug known as Liefcort were being received or held at plaintiffs' premises for use in the treatment of patients.

4. In essence, the Complaint seeks to enjoin the defendants from conducting an authorized investigation and to have the Court declare that such an investigation would be contrary to law. In addition, plaintiffs would have the Court enjoin the defendants from enforcing the provisions of the Federal Food, Drug, and Cosmetic Act against plaintiffs and to declare that the defendants lack the authority and jurisdiction to enforce the provisions of the Act against plaintiffs.

## MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

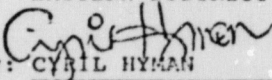
5. As established by the affidavits attached to this motion, the drug known as Liefcort is a dangerous drug which has been reported to FDA as the cause of very serious adverse effects, it is not approved under the Federal Food, Drug, and Cosmetic Act for any medical purpose, and it has been reported to the Food and Drug Administration that plaintiffs have received quantities of this drug for use in the treatment of patients. As further established by the affidavits attached to this motion, the FDA investigators involved have proceeded on instructions from their superiors in attempting to make an assigned investigation and have at all times conducted themselves in accordance with the provisions of law which authorize them to enter the premises where the plaintiffs reportedly conduct a medical practice and to make an inspection of the premises for the purpose of determining whether there are violations of the Federal Food, Drug, and Cosmetic Act. The investigators are being sued for carrying out their statutory duties, and their superiors have been joined as defendants in their capacities as officials and employees of the United States so as to make any judgment binding on the United States.

## II

The defendants further move the Court, pursuant to Rule 56 of the Federal Rules of Civil Procedure, to grant summary judgment of dismissal in favor of defendants on the grounds that there is no genuine issue as to any material fact and that defendants are entitled to judgment as a matter of law, since they are duly authorized to conduct investigations of the type attempted and in the manner in which they have been attempted.

Dated: Brooklyn, New York  
May 1, 1975

DAVID G. TRAGER  
UNITED STATES ATTORNEY  
EASTERN DISTRICT OF NEW YORK

By:   
CYRIL HYMAN  
ASSISTANT UNITED STATES ATTORNEY

MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

NOTICE OF MOTION

To: Rothblatt, Rothblatt, Seijas & Peskin, Esqs.  
232 West End Avenue  
New York, N. Y. 10023

PLEASE TAKE NOTICE, that the undersigned will bring the above motion on for hearing before the Honorable Edward R. Neaher, United States District Judge for the Eastern District of New York, at the United States Courthouse for the Eastern District of New York, 225 Cadman Plaza East, Brooklyn, New York, 11201, in Courtroom No. 2 on the 16th day of May, 1975, at 10 o'clock in the forenoon of that day or as soon thereafter as counsel can be heard.

Dated: Brooklyn, New York  
May 1, 1975

DAVID G. TRAGER  
United States Attorney  
Eastern District of New York  
Attorney for Defendants  
225 Cadman Plaza East  
Brooklyn, New York 11201

By:

*Griffithman*

CARIL HYMAN

Assistant U. S. Attorney

MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

ELIZABETH DALEY, M.D. and HENRY  
ROSENBERG, M.D.

Plaintiffs,

- against -

CASPAR W. WEINBERGER, Secretary of  
Health, Education, and Welfare, ALEXANDER  
M. SCHMIDT, M.D., Commissioner of the  
Food and Drug Administration, CLIFFORD  
G. SHANE, Regional Director of the Food  
and Drug Administration, TERRY MUSSON,  
ALLEN R. HALPER, JOHN E. KLEMMER and  
THOMAS D. GARDINE, Employees of the Food  
and Drug Administration,

AFFIDAVIT

Defendants.

Terry B. Musson, being first duly sworn, deposes  
and says:

1. I am a Supervisory Consumer Safety Officer for the  
United States Food and Drug Administration, Department  
of Health, Education, and Welfare. I have been assigned to  
the New York District office at 850 Third Avenue, Brooklyn,  
New York, since October 10, 1972.

2. My duties as a Supervisory Consumer Safety Officer  
include directing the inspectional activities of a designated  
group of professional Consumer Safety Officers and sub-  
professional personnel.

3. On February 7, 1975, in the course of my official  
duties, I issued an assignment to Consumer Safety Officer  
Allen R. Halper to conduct an inspection at the premises of  
Dr. Elizabeth Daley and Dr. Henry Rosenberg, 320 West End  
Avenue, New York, N.Y. The purpose of this inspection  
was to determine, among other things, whether a drug, Liefcort,  
was being distributed by Drs. Daley and Rosenberg.

## MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

4. On February 10, 1975, Consumer Safety Officer Halper reported to me that he was unable to conduct the inspection, since a nurse at the premises, Ms. Donna Pinorsky, advised him that the doctors were not in and would provide no further information. It was also reported to me that Ms. Pinorsky advised the investigator that Drs. Daley and Rosenberg had office hours on Wednesdays and Thursdays from 10 a.m. to 4 p.m.

5. On February 25, 1975, I called Mr. Henry Rothblatt by telephone regarding his inquiry as to FDA's jurisdiction. I informed him that we had received a report regarding the use by Drs. Daley and Rosenberg of the drug Liefcort. Among other things, Mr. Rothblatt told me that Drs. Daley and Rosenberg are not distributing Liefcort but are prescribing hormones for the treatment of their patients and that he would supply information requested by the Agency. He also advised me that on his advice Drs. Daley and Rosenberg would refuse to see FDA investigators.

6. On February 26, 1975, in the course of my official duties, I issued an assignment to Consumer Safety Officers John E. Klemmer and Thomas D. Gardine to conduct an inspection at the premises of Drs. Daley and Rosenberg at 320 West End Avenue on the following day, Thursday, February 27.

7. On February 27, Consumer Safety Officers Klemmer and Gardine reported to me that they had attempted to conduct the assigned inspection at 10:30 a.m., that Ms. Pinorsky would

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not permit them to enter the reception area of the premises,  
and had referred them to the doctors' attorneys, Rothblatt,  
Seijas, and Peskin.

TERRY B. MUSSON  
Supervisory Consumer Safety  
Officer  
New York District

County of Kings     )  
State of New York    )

Subscribed to and sworn before me at Brooklyn, New York  
this \_\_\_\_\_ day of \_\_\_\_\_, 1975.

MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

ELIZABETH DALEY, M.D. and HENRY  
ROSENBERG, M.D.

Plaintiffs,

- against -

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Food and Drug Administration, CLIFFORD  
G. SHANE, Regional Director of the Food  
and Drug Administration, TERRY MUSSON,  
ALLEN R. HALPER, JOHN E. KLEMMER and  
THOMAS D. GARDINE, Employees of the Food  
and Drug Administration,

AFFIDAVIT

Defendants.

Allen R. Halper, being first duly sworn, deposes  
and says:

1. I am a Consumer Safety Officer for the United States  
Food and Drug Administration, Department of Health, Education,  
and Welfare. I have been assigned to the New York District  
office at 850 Third Avenue, Brooklyn, New York, since  
April 19, 1971.

2. My duties as a Consumer Safety Officer include the  
inspection of establishments covered by the Food, Drug, and  
Cosmetic Act and other Acts enforced by the Food and Drug  
Administration.

3. On February 7, 1975, in the course of my official  
duties, I was given an assignment by my supervisor, Terry B.  
Mussion, Supervisory Consumer Safety Officer, to conduct an  
inspection at the premises of Drs. Elizabeth Daley and Henry  
Rosenberg, 320 West End Avenue, New York, New York. The  
purpose of this inspection was to determine, among other  
things, if the drug, Liefcort, was located on the premises  
and was being distributed for the treatment of patients.

## MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

4. I arrived at the office of Drs. Daley and Rosenberg on the morning of February 10. I identified myself as an investigator of the Food and Drug Administration to a nurse, Ms. Donna Pinorsky, showed my credentials, and issued to her a Notice of Inspection. I explained to her the purpose of my visit. Ms. Pinorsky told me that Drs. Daley and Rosenberg had hours on Wednesday and Thursday from 10 a.m. to 4 p.m. She stated that she would not give me any information about the operation of the doctors' practice. She further stated that any information about the doctors would have to come from their attorneys, Rothblatt, Seijas, and Peskin, located at 232 West End Avenue, New York, New York. She also advised me that even if I visited during the office hours of the doctors I would be referred to their attorneys.

5. On leaving the premises of Drs. Daley and Rosenberg, I went to the office of the attorneys to whom I had been referred. I was told by the receptionist that Henry Rothblatt was in court and that I should call for an appointment on the following day. I then returned to the District office to report my findings.

6. On February 10, 11, and 12, 1975, I spoke to Mr. Henry Rothblatt by telephone. During these conversations I advised Mr. Rothblatt that the Food and Drug Administration wanted to obtain information on the use of the drug Liefcort by Drs. Daley and Rosenberg. Among other things, Mr. Rothblatt told me that even before the death of the originator of Liefcort, there had been no

MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

such drug as Liefcort. However, Mr. Rothblatt also told me that Drs. Daley and Rosenberg use a form of treatment that was conceived by Dr. Liefmann.

\_\_\_\_\_  
ALLEN R. HALPER  
Consumer Safety Officer  
New York District

County of Kings     )  
State of New York    )

Subscribed to and sworn before me at Brooklyn, New York  
this \_\_\_\_\_ day of \_\_\_\_\_, 1975.

\_\_\_\_\_

MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

ELIZABETH DALEY, M.D. and HENRY  
ROSENBERG, M.D.

Plaintiffs,

- against -

CASPAR W. WEINBERGER, Secretary of  
Health, Education, and Welfare, ALEXANDER  
M. SCHMIDT, M.D., Commissioner of the  
Food and Drug Administration, CLIFFORD  
G. SHANE, Regional Director of the Food  
and Drug Administration, TERRY MUSSON,  
ALLEN R. HALPER, JOHN E. KLEMMER and  
THOMAS D. GARDINE, Employees of the Food  
and Drug Administration,

AFFIDAVIT

Defendants,

John E. Klemmer, being first duly sworn, deposes  
and says:

1. I am a Consumer Safety Officer for the United States  
Food and Drug Administration, Department of Health, Education,  
and Welfare. I have been assigned to the New York District  
office at 850 Third Avenue, Brooklyn, New York, since  
August 18, 1971.

2. My duties as a Consumer Safety Officer include the  
inspection of establishments covered by the Food, Drug, and  
Cosmetic Act and other Acts enforced by the Food and Drug  
Administration.

3. On February 26, 1975, in the course of my official  
duties, I was given an assignment by my supervisor, Terry B.  
Musson, Supervisory Consumer Safety Officer, to conduct an  
inspection at the office of Dr. Elizabeth Daley and Dr. Henry  
Rosenberg, 320 West End Avenue, New York, New York. The purpose  
of this inspection was to determine, among other things,  
whether the drug, Liefcort, was located on the premises and being  
distributed for the treatment of patients. I was accompanied  
by Consumer Safety Officer Thomas D. Gardine.

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4. Consumer Safety Officer Gardine and I arrived at the office at approximately 10:30 a.m. on Thursday, February 27. We found the door to the office locked. We rang the bell outside the door and a Ms. Donna Pinorsky opened the door. We identified ourselves as investigators of the Food and Drug Administration, showed our credentials, and issued to her a Notice of Inspection.

5. We asked Ms. Pinorsky if we could speak to Drs. Daley and Rosenberg. Ms. Pinorsky refused to let us enter the reception area. She said that we would have to speak to the doctors' attorneys, Rothblatt, Seijas, and Peskin. She also told us that the doctors were not in the office that day. Investigator Gardine and I then left the office and returned to the District office to report our findings.

\_\_\_\_\_  
JOHN E. KLEMMER  
Consumer Safety Officer  
New York District

County of Kings       )  
State of New York    )

Subscribed to and sworn before me at Brooklyn, New York  
this \_\_\_\_\_ day of \_\_\_\_\_, 1975.

\_\_\_\_\_

MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK  
-----

ELIZABETH DALEY, M.D. and HENRY  
ROSENBERG, M.D.

Plaintiffs,

- against -

CASPAR W. WEINBERGER, Secretary of  
Health, Education, and Welfare, ALEXANDER  
M. SCHMIDT, M.D., Commissioner of the  
Food and Drug Administration, CLIFFORD  
G. SHANE, Regional Director of the Food  
and Drug Administration, TERRY MUSSON,  
ALLEN R. HALPER, JOHN E. KLEMMER and  
THOMAS D. GARDINE, Employees of the Food  
and Drug Administration,

AFFIDAVIT

Defendants.  
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George J. Gerstenberg, being first duly sworn, deposes  
and says:

1. I am Deputy Regional Food and Drug Director,  
New York District of the Food and Drug Administration,  
Department of Health, Education, and Welfare, 850 Third  
Avenue, Brooklyn, New York. I direct and supervise the  
day-to-day enforcement of the Federal Food, Drug, and  
Cosmetic Act for the United States Food and Drug  
Administration, New York District, which includes New York  
City and the counties of Nassau, Suffolk, Westchester and  
Rockland.

2. On or about September 30, 1974, the New York District  
office was notified by Mr. Paul Sage of the Bureau of Drugs,  
Food and Drug Administration, Rockville, Maryland, that the  
Food and Drug Administration had received a report that  
Liefcort, a new drug for which no approved New Drug Appli-  
cation is in effect, had been received after shipment in  
interstate commerce by Dr. Elizabeth Daley and Dr. Henry  
Rosenberg at their office at 320 West End Avenue, New York,  
New York, and was being used for the treatment of patients.

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The files of FDA's New York District Office include reports demonstrating the hazardous nature of this drug and the basis for its illegality under the Federal Food, Drug, and Cosmetic Act. See, for example, the attached report issued by the Arthritis Foundation, 1212 Avenue of the Americas, New York, N.Y. 10036.

3. Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355, new drugs shall not be distributed in interstate commerce unless evidence of safety and effectiveness is submitted to the Food and Drug Administration and approved by that Agency. Distribution of a product classified as a new drug which lacks evidence of safety and effectiveness is an unwarranted threat to the public health and safety.

4. In the course of my official duties, I initiated a preliminary investigation of the report that Drs. Daley and Rosenberg had received the drug Liefcort and obtained information which led me to believe that the doctors were distributing the drug. Accordingly, I ordered a formal inspection of their premises at 320 West End Avenue, New York, N.Y.

\_\_\_\_\_  
GEORGE J. GERSTENBERG  
Deputy Regional Food  
and Drug Director  
New York District

County of Kings     )  
State of New York    )

Subscribed to and sworn before me at Brooklyn, New York  
this \_\_\_\_\_ day of \_\_\_\_\_, 1975.

## MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

- ☐ On May 2, 1953, Canadian Food and Drug Directorate authorities "raided" Dr. Liefmann's clinic in Montreal and seized "all available supplies" of his medicines. Subsequently he was charged on 16 counts of violation of the Canadian Food and Drug Act and trial began in June. The charges included selling an untested drug, selling controlled drugs without prescription, violating labeling regulations, and selling drugs prepared under unacceptable conditions.
- ☐ Although he has been quoted many times as saying he is willing to, Dr. Liefmann has not at this writing made the formula for his medication public; nor has he applied for approval from Federal drug authorities.

This special report discusses the situation at this time under the following headings:

1. Background
2. Liefcort
3. Robert Liefmann, M.D. and his Clinic
4. Liefmann/Liefcort Promotion
5. In Sum

### BACKGROUND

Dr. Liefmann and Liefcort first attracted wide public attention in May 1962 when Look Magazine published an article on him. At that time he was not even a licensed M.D., having failed his examination. Later that year he passed a re-examination and was licensed to practice in Canada by the Quebec College of Physicians and Surgeons.

Banned. The Canadian Food and Drug Directorate prohibited the retail sale of Liefcort and distribution of it to Canadian doctors for investigational purposes, because of the lack of laboratory quality control to insure composition and safety in its manufacture.

Reactions. After several arthritis patients in the U.S., who had visited Montreal and obtained and taken the drug, suffered serious reactions, the U.S. Food and Drug Administration denounced it as "imminently dangerous" and banned its importation into the U.S.

Dr. Liefmann's Montreal clinic continued to operate, with patients from Canada and the U.S. visiting it, for several years with relatively little public fanfare or publicity.

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In early 1962, when various authorities in Canada were preparing to investigate Dr. Liefmann's practices, and he was facing possible prosecution, he called a press conference in Montreal to talk about his alleged success in treating victims of arthritis.

Publicity. Since then, judged by the increase in inquiries about Liefmann and Liefcort received by The Arthritis Foundation, and by reports coming to it from various sources, a stepped-up publicity campaign is being waged. A book about Dr. Liefmann and his claims has been published and widely distributed and advertised in the U.S. It is apparent that more and more U.S. arthritis patients are traveling to Montreal to obtain supplies of the contraband formula.

### LIEFCORT

Back in 1962, Dr. Liefmann gave the name of his principal arthritis medication as "Liefcort." Recently he has been quoted in newspaper stories as saying he should never have given it a trade name. In describing his arthritis treatment method in written materials distributed in 1962, the name "Liefcort" is not mentioned. However, an arthritis patient on the staff of The Arthritis Foundation visited his Montreal clinic in March 1962 and was given an eyedropper with the word "Liefcort" printed on it, to use in measuring out doses of the medicine he bought.

Analysis. Liefcort, a liquid, was analysed in 1962 by the FDA and by a laboratory to which The Arthritis Foundation submitted samples. Again in 1962, the Foundation obtained a sample and turned it over to the FDA for analysis. In both years, the chief ingredients were found to be prednisone (one of the cortisones), testosterone (a male hormone), and estradiol (a female hormone).

Inconsistency. Several samples of Dr. Liefmann's medication were analysed by Canadian authorities in mid-1962 and were found to have similar ingredients. It was noted that the relative amount of prednisone -- the steroid drug compound -- in each bottle tested varied from bottle to bottle. In both Canada and the U.S., the manufacturer of an approved drug is required to have its contents precisely the same from batch to batch and bottle to bottle so that the physician prescribing it can be sure of the exact dosage his patients are receiving.

Nothing Special. Prednisone, testosterone and estradiol are well-known drugs, and have been used, separately and together, in treating arthritis for years. There is nothing "magic" or "special" about their use. Nobody needs to go to Canada to get these hormones. But competent doctors in the United States would be unlikely to prescribe them for arthritis in this combination and in the amounts compounded by Dr. Liefmann.

Temporary Relief. Prednisone can give very dramatic relief from the symptoms of arthritis. It can reduce inflammation and take away pain. It can make a joint stiffened by arthritis limber again. When cortisone was first discovered in 1949, physicians were excited by its potential for controlling arthritis. They soon found, however, that its effects were temporary.

## MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

Side Effects. As soon as patients stopped taking it, the symptoms came back. If they kept on taking it, many of them developed some serious side effects...such as moon face, internal bleeding, peptic ulcers, softening of bones with spontaneous fractures, mental disturbances, and damage to liver, kidneys and other vital organs. "Cortisones," including prednisone, are still prescribed for arthritis, but only under regular supervision of the doctor, and with dosage very carefully regulated. Most physicians specializing in arthritis treatment today prefer not to use this type of drug except as a last resort.

Risk. So the arthritis sufferer who obtains a supply of Liefcort to last a month or more may get welcome relief, but is taking a grave risk of dangerous side effects...and he is certainly not going to be "cured" in a sense that he will be free of the disease as a result of taking this medicine. Arthritis sometimes goes away by itself, even when nothing is being taken for it. When this happens with a patient who is taking something, the natural tendency is to ascribe the "cure" to whatever was being taken. Liefcort may have gained an undeserved reputation in this way with some patients.

The male and female hormones, testosterone and estradiol, may reduce the toxic effects of prednisone. But these hormones can have serious side effects themselves. There are reports of men taking Liefcort who have developed enlarged breasts and women who have grown beards. Menstrual disturbances are common.

At least three deaths have been reported as the direct or indirect result of taking Liefcort. Many physicians in the U.S. have reported serious problems with their patients who visited Dr. Liefmann's Montreal clinic and took his medicines.

### ROBERT LIEFMANN, M.D. AND HIS CLINIC

Visitors to the Liefmann clinic have reported that only a precursory examination was made before medicine was prescribed and sold to patients. According to a story in April 18, 1968 issue of the MONTREAL GAZETTE, researchers for the newspaper were able to obtain bottles of Liefcort by writing and sending money without even visiting the clinic for examination. One of these researchers, the story said, didn't have arthritis in the first place.

Following the search-and-seizure carried out by Canadian Food and Drug Directorate inspectors in Dr. Liefmann's clinic in May 1968, he has continued to practice, but is reported to have changed his procedures. At least some examination is now required, and patients must fill out a long questionnaire.

An article in the March 29, 1968 issue of MEDICAL WORLD NEWS, which sent a reporter to visit Dr. Liefmann in his Montreal clinic offices, states: "He says his charges are \$15 for an initial examination and \$10 to \$15 for medication, but his patients report that they are higher. Even at the rates he admits to, however, Dr. Liefmann's gross income may reach \$250,000 annually."

## MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

Cost of Medicine. That would appear to be conservative. The bottle of medicine which used to cost \$10 or \$15 was a half-ounce bottle. The MONTREAL GAZETTE reported on June 18, 1968 that "the half-ounce bottle is no longer available. Patients must buy a six-ounce quantity -- or nothing. This means that men pay \$180 while women -- who receive two bottles -- pay \$360." Many reports indicate that his waiting rooms are crowded and that he sees from 30 to 40 or more patients a day. At this rate, the Liefmann operation would be grossing more than \$3,000,000 a year.

Unsanitary Conditions. How is his Liefcort formula put together, or "manufactured"? According to reports, Dr. Liefmann mixes it himself, and only he has the formula. A MONTREAL GAZETTE story in its issue of September 6, 1968 said that trial witnesses testified to unsanitary conditions in the laboratory used for preparing and bottling Dr. Liefmann's arthritis remedies...such as dust deposits and dirty food dishes on laboratory tables. A Liefmann laboratory assistant who worked at bottling medicines for him testified, the paper reported, that the utensils used were not sterilized "as far as I know."

Suspension of License. When (on May 1, 1968) the Council of Discipline of the Quebec College of Physicians and Surgeons suspended Dr. Liefmann's license to practice medicine in the Province of Quebec for five years, it announced that he had been found "guilty of having taken as associates or employees two persons not authorized to practice medicine in the Province of Quebec and for having permitted these two persons to practice medicine in his office and in his name." In announcing the suspension, the MONTREAL GAZETTE identified these two persons as "a former clerk" and "an unlicensed European practitioner."

The following is quoted from an "AMA Data Sheet on Liefcort," dated 1968:

"Robert Liefmann studied medicine at the McGill University Faculty of Medicine in Canada. In 1954 he took the examination for licensing as a private practitioner, but failed the oral examination in surgery. In 1962 he passed this examination and was certified by the Quebec College of Physicians and Surgeons to practice medicine in Canada. Prior to his licensure he worked as a researcher at Montreal's Royal Victoria Hospital. He was suspended by the hospital for implanting the pituitary glands of newly slaughtered calves into the thighs of six arthritis patients. He was later reinstated but then left his position, and set up a commercial operation called Endocrine Research Laboratories, which created and distributed hair tonics, hair-growing preparations, and vitamin preparations.

"On December 10, 1957 a warrant for the arrest of Liefmann was issued in the United States, on charges of introducing a misbranded drug into interstate commerce in violation of the U.S. Federal Food, Drug and Cosmetic Act. The case involved an alleged baldness cure called 'R-20,' distributed by Liefmann, which contained the female sex hormone estradiol and isopropyl alcohol. FDA charged that the preparation was both worthless and dangerous. Liefmann failed on several occasions to appear in

## MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

Federal District Court in Syracuse, New York, for arraignment, and an arrest warrant was issued. He still faces prosecution on the charges if and when he comes to the United States."

### LIEFCORT/LIEFMANN PROMOTION

The most effective promotion of Dr. Liefmann and his remedy, attracting patients in the U.S. to his Montreal clinic, seems to be the result of word-of-mouth reports between and among arthritis patients and their friends and families. Arthritis sufferers are prone to try anything which they think may help them.

Gobbledegook. Dr. Liefmann distributes a document titled, "Rationale for the use of the Liefmann Metabolic Method in the Treatment of Rheumatic and Arthritic Diseases." It is a compilation of fine-sounding medical gobbledegook. It mixes fact with misstatement of fact and outright fiction. It claims that rheumatic diseases are essentially a matter of hormone imbalance. There is no reliable medical evidence that this is so. Throughout, it downgrades the use of corticosteroid drugs in the treatment of rheumatic diseases. Yet one of the principal ingredients in Liefcort, which is prescribed as part of the "Liefmann Method," is prednisone, which is itself a corticosteroid drug.

"Arthritis Discovery." In 1968, a paperback book was published and is now being sold in the United States and Canada. Its title is "Arthritis Discovery." A subtitle on the flyleaf reads, "The Attempted Murder of Canadian Arthritis Discovery -- The Crime Plotted by the Medical-Drug Cartel, Pseudo-Charity, Establishment."

The book lists no author or editor, but is "Dedicated to the Robert Liefmann Clinic" in Montreal. It contains the Liefmann "Rationale" and transcripts of radio broadcasts in Canada, interview style, in which Dr. Liefmann makes various claims for the effectiveness of his methods of treating arthritis. It also contains an attack on the "conspiracy" of the "Establishment" against medical progress, as Dr. Liefmann sees it.

It was first published in Canada in January 1968 and later in Freeport, Bahamas. Advertisements for it, which have been placed in newspapers in the U.S., do not mention Dr. Liefmann or Liefcort by name, but provide a Montreal address from which it may be ordered.

The Arthritis Foundation considers the book a reprehensible document calculated to induce more arthritis sufferers to go to Canada to obtain a contraband and dangerous drug.

### IN SUM

Dr. Robert Liefmann of Montreal, Canada, makes and sells for his own profit medications (the chief one formerly called "Liefcort") which he claims have been successful in treating and "curing" patients with rheumatoid arthritis.

## MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

He has repeatedly made the statement that his remedy is available for testing and that the medical profession and others have hindered and prevented this. His "Rationale" concludes with: "...The persons in charge are remiss in their duties if they fail to conduct controlled clinical investigations into any method that may be of help in the treatment of patients suffering from these diseases and to promptly make the results available to the public through factual presentation. Anything less is cheating the public."

So far as officials of The Arthritis Foundation are aware, Dr. Liefmann has yet to reveal or give the full details of his formula to any organization or medical authority so that such testing of it could be undertaken. He has not taken even the first step toward seeking federal drug approval of his medication for arthritis. Meanwhile, he alone sells it, for personal profit.

From this, one can conjecture who is doing what to the public.

For a number of years the American Medical Association has published a list of six "simple rules" to help "a non-medical person recognize a health quack" or questionable practitioner, essentially as follows:

1. He often uses a "special" or "secret" formula or machine that he claims can cure disease.
2. He may promise or imply a quick or easy cure or improvement.
3. He advertises or uses "case histories" and testimonials from his patients to impress people.
4. He refuses to accept the tried and proved methods of medical research and proof. He clamors constantly for "medical investigation" and recognition, but he avoids testing or stops short of giving the data needed for a scientific evaluation.
5. He frequently claims medical men are persecuting him or that they are afraid of his competition.
6. He claims that his method of treatment is better than drugs and other measures prescribed by physicians generally.

It is left to the reader to judge whether any of the above guidelines appear to apply to Dr. Liefmann's practices.

\* \* \*

The Foundation warns arthritis patients not to use the drug preparation Liefcort in the treatment of their disease.

\* \* \*

MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

-----

ELIZABETH DALEY, M.D. and HENRY  
ROSENBERG, M.D. -----

Plaintiffs,

-against-

CASPAR W. WEINBERGER, Secretary of  
Health, Education, and Welfare, ALEXANDER  
M. SCHMIDT, M.D., Commissioner of the  
Food and Drug Administration, CLIFFORD  
G. SHANE, Regional Director of the Food  
and Drug Administration, TERRY MUSSON,  
ALLEN R. HALPER, JOHN E. KLEINER and  
THOMAS D. GARDINE, Employees of the Food  
and Drug Administration,

AFFIDAVIT

Defendants.

-----

Paul J. Sage, being first duly sworn, deposes, and says:

1. I am a Consumer Safety Officer in the Division of  
Drug Manufacturing of the Bureau of Drugs of the United States  
Food and Drug Administration.

2. In September 1974, I was an Assistant to the  
Director of the Division of Regulatory Operations of the  
Bureau of Drugs. My official duties in this capacity in-  
cluded-determining the Agency investigative action with re-  
spect to reports concerning use and possible illegal distri-  
bution of unapproved new drugs.

3. In late September 1974, in the course of my official  
duties, I received a report indicating Drs. Henry Rosenberg  
and Elizabeth Daley of New York City were dispensing or using a  
drug known as Leifcort. There appeared to be a possibility  
the drug was being or had been shipped into the United States  
from Canada.


4. Leifcort is known to the Agency as a proprietary  
name for a drug that has been promoted abroad for use in  
treating arthritis. FDA files indicate that it is a drug

MOTION TO DISMISS AND FOR SUMMARY JUDGEMENT

containing an irrational mixture of potent hormones which has not been approved under the requirements of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355, for use in the treatment of arthritis. Our records indicate there have been reports of very serious adverse effects attributed to the drug.

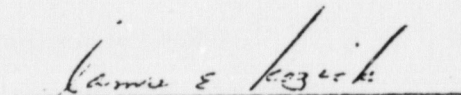
5. For the above reasons, on September 30, 1974, in the course of my official duties, I issued an assignment to FDA's New York District office requesting that an investigation be made to determine, among other things, whether the drug was in the possession of the doctors concerned. I authorized the district to investigate the matter either directly, by making an inspection, or indirectly through securing cooperation of New York State authorities.

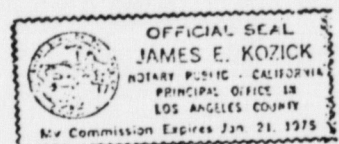
6. Should an investigation by our district office or by cooperating authorities result in the discovery of illegal stocks of Leifcort within the jurisdiction of the Federal Food, Drug, and Cosmetic Act, the Agency would initiate consideration of appropriate regulatory or other action under the Act for the protection of consumers.

  
Paul J. Sage

County of Los Angeles    )  
State of California        )

Subscribed and sworn to before me this 24<sup>th</sup> day of  
APRIL, 1975.

  
Notary Public



STATEMENT PURSUANT TO RULE 9(G)

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

-----x  
ELIZABETH DALEY, M.D., :  
 :  
Plaintiff, : STATEMENT PURSUANT  
 : TO RULE 9(g) OF  
-against- : THE GENERAL RULES  
 : OF THIS COURT  
CASPAR W. WEINBERGER, Secretary of :  
Health, Education and Welfare, : Civil Action  
ALEXANDER M. SCHMIDT, M.D., : No. 75 C 306  
Commissioner of the Food and Drug  
Administration, CLIFFORD G. SHANE, :  
Regional Director of the Food and  
Drug Administration, TERRY MUSSON, :  
ALLEN R. HALPER, JOHN E. KLEMMER, :  
and THOMAS D. GARDINE, Employees :  
of the Food and Drug Administration, :  
Defendants. :  
-----x

The following are material facts as to which the  
Federal defendants contend there is no genuine issue to be  
tried:

1. The plaintiff herein, ELIZABETH DALEY, M.D.,  
holds in her office drugs (within the meaning of 21 U.S.C.  
§321(g)(1)) which have been shipped in interstate commerce.

2. On February 10, 1975 F.D.A. Consumer Safety  
Officer Allen R. Halper arrived at the offices of plaintiff  
ELIZABETH DALEY, M.D., identified himself as an F.D.A.  
inspector, showed his credentials, and issued a notice of  
inspection. The purpose of the inspection was to determine,  
in response to certain information which had come to the  
attention of the F.D.A., if certain drug products which had  
been shipped in interstate commerce were present in the  
doctor's office. Inspector Halper was refused admission to  
the office by plaintiff's nurse, Ms. Donna Pinorsky, R.N.,  
and was advised to consult plaintiff's attorneys, Rothblatt,  
Rothblatt, Seijas and Peskin.

3. At approximately 10:30 A.M. on February 27,  
1975, F.D.A. Consumer Safety Officers John E. Klemmer and  
Thomas O. Gardine arrived at the offices of plaintiff

STATEMENT PURSUANT TO RULE 9(G)

ELIZABETH DALEY, M.D., identified themselves as F.D.A. inspectors, showed their credentials, and issued a notice of inspection. The purpose of the inspection was to determine in response to certain information which had come to the attention of the F.D.A., if certain drug products which had been shipped in interstate commerce were present in the doctor's office. Inspectors Klemmer and Gardine were refused admission to the office by plaintiff's nurse, Ms. Donna Pinorsky, R.N., and were advised to consult plaintiff's attorneys, Rothblatt, Rothblatt, Seijas and Peskin.

4. This action was filed on March 6, 1975, prior to any further investigative activity.

Dated: Brooklyn, New York  
July 3, 1975

DAVID G. TRAGER  
United States Attorney  
Eastern District of New York  
Attorney for Defendants  
225 Cadman Plaza East  
Brooklyn, New York 11201

By: 

CYRIL HYMAN  
Assistant U. S. Attorney

COUNTERSTATEMENT PURSUANT TO LOCAL RULE 9 (G)

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

---

ELIZABETH DALEY, M.D. and HENRY  
ROSENBERG, M.D.,

Plaintiffs,

-against-

CASPAR W. WEINBERGER, Secretary of  
Health, Education and Welfare,  
et al.,

Defendants.

---

COUNTERSTATEMENT  
PURSUANT TO LOCAL  
RULE 9 (g).

75- C-306

The material facts as to which plaintiff contends  
there exists a genuine issue to be tried include the following:

1. Precisely when and for what reason did the FDA commence an investigation of Dr. Elizabeth Daley and Dr. Henry Rosenberg? What is the factual basis for the investigation, and the source of any information received concerning the doctors and their medical practice?
2. What is the factual and legal basis for the FDA's claim of jurisdiction over plaintiff?
3. Precisely which provisions of the Federal Food, Drug and Cosmetic Act does the FDA contend plaintiff has or may have violated, and is there a factual basis for this contention?
4. What is the factual basis for the FDA's contention that plaintiff administers "dangerous" and "hazardous" medication to her patients? When, where and how did the FDA obtain samples of

COUNTERSTATEMENT PURSUANT TO LOCAL RULE 9(G)

medications administered by plaintiff? Who analyzed these samples and what were the results of the analysis? Who determined the medications are hazardous and what is the scientific basis for this conclusion?

5. What is the chemical composition of "Liefcort"?

6. Did plaintiff ever receive interstate shipment of "Liefcort"?

7. When, where and how did plaintiff distribute "Liefcort", and to whom?

8. What is the factual basis for the FDA's conclusion that "Liefcort" is hazardous and produces severe side effects?

9. Has plaintiff refused to permit authorized entry and inspection, or has plaintiff adulterated, misbranded or mislabeled any food, drug, device, or cosmetic within the meaning of 21 U.S.C. 331 (f), (k), (l)?

10. Has plaintiff introduced any "new" drugs into interstate commerce in violation of 21 U.S.C. 331 (d)?

11. What was the purpose of the February 10, 1975 entry and inspection of plaintiff's medical office? Precisely what items did the inspectors intend to examine and/or seize?

12. Did plaintiff's nurse refuse to permit authorized entry and inspection within the meaning of 21 U.S.C. 331 (f)?

13. What was the purpose of the February 27, 1975 entry and inspection of plaintiff's medical office? Precisely what items did the inspectors intend to examine and/or seize?

COUNTERSTATEMENT PURSUANT TO LOCAL RULE 9(G)

14. Did plaintiff's nurse refuse to permit authorized entry and inspection within the meaning of 21 U.S.C. 331 (f)?

15. Does plaintiff hold in her office any unapproved drugs which have been shipped in interstate commerce?

16. Is plaintiff's medical office a "factory, warehouse, or establishment" within the meaning of 21 U.S.C. §374?

17. Does plaintiff hold in her office any "food, drugs, devices, or cosmetics" within the meaning of 21 U.S.C. §374?

18. Was this action filed on February 28, 1975, the day after the second notice of inspection was served upon plaintiff's nurse?

Dated: New York, New York  
July 7, 1975

Respectfully submitted,

ROTHBLATT, ROTHBLATT, SEIJAS  
and PESKIN  
Attorneys for Plaintiff  
by

---

JON G. ROTHBLATT  
232 West End Avenue  
New York, New York 10023  
212-787-7001

1 packages of the pharmaceuticals that we received.  
2 Certainly, we're not ashamed of those.

3 THE COURT: That's why I keep wondering why  
4 we're here.

5 MR. ROTHBLATT: If they tell us what they want  
6 we'll give it to them. We don't want them rummaging  
7 through our office. When they used the word "Leafcourt"  
8 it showed bad faith.;

9 THE COURT: Mr. Hyman, you indicate you would  
10 be present?

11 MR. HYMAN: Absolutely.

12 MR. ROTHBLATT: Fine. If Mr. Hyman and I agree  
13 on what he said, we'll withdraw our case. If he says  
14 that what they all want to do is precisely what he  
15 said, this is not what the inspector said. I'm happy  
16 to work it out. We don't want to make cases here.

17 THE COURT: Perhaps the time is right for  
18 Mr. Hyman and Mr. Rothblatt to agree upon a time and  
19 place wherein an inspector may come up there and do what  
20 the inspector was going to do in the first place.

21 MR. HYMAN: Well, your Honor, the problem with  
22 an agreed time and place --

23 THE COURT: I mean, place, of course, would have  
24 to be the doctor's office.

25 MR. HYMAN: Agreed time is really -- doesn't make

1 it an inspection. It makes it a meeting.

2 THE COURT: Law says, a reasonable time. So I  
3 assume two reasonable men can agree on a reasonable  
4 time.

5 MR. HYMAN: The problem of that, as I under-  
6 stand, what the law says --

7 THE COURT: Well, you have to comply.

8 MR. HYMAN: If your Honor please, if I was your  
9 superior and I wanted to see what you were doing, I  
10 wouldn't call you up and say, look, I am going to come  
11 down three weeks from now and by that time if you're  
12 doing something that shouldn't be done you wouldn't be  
13 doing it any more. That's the type of thing that we  
14 ask an inspector for.

15 THE COURT: Now, you're suggesting that some  
16 kind of hanky-panky --

17 MR. HYMAN: No. We don't know. I am relying on  
18 what Mr. Rothblatt says. There is nothing going on.  
19 But that doesn't mean the agents or the agency has to --

20 THE COURT: I am not suggesting what the agent  
21 will think, see or do. I am simply suggesting it  
22 would appear that an agent may complete the inspections  
23 so long as Mr. Rothblatt is present.

24 MR. HYMAN: There is no problem. The agent  
25 could come in and the doctor could call up

1 Mr. Rothblatt's office.

2 THE COURT: All I'm suggesting, you get together  
3 and work out a definite time to be accomplished.

4 MR. HYMAN: We don't have the authority to do  
5 that, your Honor.

6 THE COURT: Are you suggesting you do not wish  
7 to have Mr. --

8 MR. HYMAN: I am suggesting that Mr. Rothblatt  
9 may be present.

10 THE COURT: Yes.

11 MR. HYMAN: But I am -- what I am saying, I  
12 cannot make an arrangement to have an inspector be  
13 there at a definite time for Mr. Rothblatt. In other  
14 words, the inspection is just what it is, an inspection.

15 THE COURT: Are you suggesting that you will  
16 choose a time or date?

17 MR. HYMAN: Which is reasonable.

18 THE COURT: But with an opportunity, then, when  
19 the --

20 MR. HYMAN: Yes.

21 THE COURT: Inspector arrives to have  
22 Mr. Rothblatt? But, of course, Mr. Rothblatt is a  
23 busy lawyer.

24 MR. HYMAN: He has four, five associates.

25 MR. ROTHBLATT: I want to make certain that I've

1 gone a long way. I want to make certain that what  
2 we're doing is precisely what you said we can do.

3 MR. HYMAN: That's the Government's position.  
4 In other words, it couldn't be that important that an  
5 associate of Mr. Rothblatt couldn't be present. That  
6 the inspection will take place reasonable time,  
7 reasonable manner. That the inspector will wait a  
8 reasonable time, ten minutes.

9 MR. ROTHBLATT: We can't agree, Judge. So what  
10 I said, his original offer, it was Mr. Hyman's offer,  
11 not the Department's offer. That's why we're in this  
12 Court because we charged them with bad faith. When  
13 they use that word "Leafcourt" they base their report,  
14 their right to inspect upon a 1968 report of the  
15 Arthritis Foundation on a medicine that they knew no  
16 longer exists, hasn't existed since 1958, I charge  
17 the Government with bad faith and that's why we're in  
18 this Court to vindicate our rights.

19 THE COURT: Well, I think you got a problem on  
20 your hands because I think if the Government doesn't  
21 wake up, it's going to have a decision holding that the  
22 exemption applies here. So you'd better think that one  
23 over.

24 Now, you're not dealing with a drug establishment,  
25 a warehouse, a factory or any other thing spelled out

1 here. The word "physician's office" isn't mentioned in  
2 that notice. Now, you can either take half a loaf or  
3 perhaps lose it all. I should think a doctor would  
4 have the right to have counsel present in such a  
5 situation.

6 MR. HYMAN: I think the Court is misunderstanding  
7 what we're saying. If counsel wants to be there, he  
8 can be there. The inspection provision provides for an  
9 inspection.

10 THE COURT: At a reasonable time and place.

11 MR. HYMAN: At a reasonable time and place.

12 THE COURT: Why do you suppose that is entirely  
13 within the discretion of the Department and no one else?

14 MR. HYMAN: During the operating hours of the  
15 physician's office.

16 THE COURT: Well, in this case, as I'm pointing  
17 out to you, you are not entering a factory, warehouse  
18 or establishment. You're entering what is alleged to  
19 be and I presume is not denied, a doctor's office.

20 MR. HYMAN: That's correct, your Honor. But  
21 we say, maintain an establishment is a doctor's office.

22 THE COURT: I understand. You maintain that,  
23 but in view of the clear-cut exception spelled out in  
24 another part of the statute and the ambiguity as to  
25 its scope, I suggest taking that. Since this does

1 appear to be somewhat unusual, despite your statement  
2 not supported, of course, although I wouldn't deny it,  
3 I assume you could supply an affidavit that doctors'  
4 offices are customarily inspected; is that so?

5 MR. HYMAN: Mr. Patterson from the Food and Drug  
6 Administration makes that representation.

7 THE COURT: All right. I'll accept that. But I  
8 do suggest that in the circumstances here, a reasonable  
9 time and place and the opportunity for counsel to be  
10 present ought to be seriously considered.

11 MR. HYMAN: Excuse me.

12 THE COURT: The fact there have been no prior  
13 cases doesn't mean they'll not be a first case because  
14 someone wishes to contest the matter.

15 MR. HYMAN: I've been informed, your Honor, that  
16 under the act we have no authority to make that  
17 representation.

18 THE COURT: All right. All right, do you want  
19 to consider the matter submitted?

20 MR. ROTHBLATT: Yes, your Honor.

21 MR. HYMAN: Thank you very much.

22 MR. ROTHBLATT: One case, your Honor, the fact  
23 Mr. Hyman has cited a statute which gives the party an  
24 opportunity to have a hearing before enforcement,  
25 before a criminal proceeding is brought, the Supreme

1 Court has construed that statute. I am just citing  
2 one case that's noted under the statute in the  
3 annotations where it was held that "compliance with  
4 this chapter, that is, requiring administrative, before  
5 reporting a violation for prosecution to give the  
6 suspect an opportunity to present his views is not a  
7 prerequisite to prosecution."

8 So the Supreme Court has construed that statute  
9 and I --

10 MR. HYMAN: The case is United States v. Dotter-  
11 weich, and that's reported at 320 U.S. 277.

12 Your Honor, I read the statute for just for what  
13 it said.

14 THE COURT: Well, I am assuming you are not  
15 misreading it, but Mr. Rothblatt is pointing out the  
16 Supreme Court has a different view of it.

17 MR. HYMAN: As you know, the courts take  
18 different views --

19 THE COURT: That happens to be a court no one  
20 can disagree with.

21 \* \* \*

MEMORANDUM AND ORDER  
OF HON. EDWARD R. NEAHER

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

-----X

ELIZABETH DALEY, M.D., :

Plaintiff, :

-against- :

75 C 306

CASPAR W. WEINBERGER, Secretary :

of Health, Education and Welfare, :

ALEXANDER M. SCHMIDT, M.D., :

Commissioner of the Food and Drug :

Administration, CLIFFORD G. SHANE, :

Regional Director of the Food and :

Drug Administration, TERRY MUSSON, :

ALLEN R. HALPER, JOHN E. KLEMMER :

and THOMAS D. GARDINE, Employees of:

the Food and Drug Administration, :

Defendants. :

-----X

MEMORANDUM  
AND  
ORDER

APPEARANCES:

ROTHBLATT, ROTHBLATT, SEIJAS  
& PESKIN, ESQS.

Attorneys for Plaintiff  
By HENRY B. ROTHBLATT, ESQ.  
JON G. ROTHBLATT, ESQ.

DAVID G. TRAGER, ESQ.  
United States Attorney,  
Eastern District of New York  
Attorney for Defendants  
By CYRIL HYMAN, ESQ.  
Assistant U.S. Attorney

NEAHER, District Judge.

MEMORANDUM AND ORDER OF  
HON EDWARD R. NEAHER

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Plaintiff Elizabeth Daley, a licensed physician practicing in New York City, brought this action under 28 U.S.C. §§1331 and 1337 seeking declaratory and injunctive relief aimed at preventing defendants (hereinafter "FDA") from any further attempts to conduct an inspection of her office. The case is now before the court on FDA's motion to dismiss the complaint or in the alternative for summary judgment. Rules 12(b)(6) and 56, F.R.Civ.P.

In the course of plaintiff's practice it appears that she prescribes various drugs, including prednisone, testosterone, estradiol and combinations thereof, for patients suffering from rheumatic diseases, principally rheumatoid arthritis. She alleges that on or about February 10, 1975, defendant Allen R. Halper, an FDA investigator, visited her office in New York City, interrogated a registered nurse in her employ and served a Notice of Inspection pursuant to Section 704(a) of the Food, Drug and Cosmetic Act, 21 U.S.C. §374(a) ("the Act").<sup>1</sup> On or about February 27, 1975, two other FDA investigators, defendants John E. Klemmer and Thomas D. Gardine, appeared at plaintiff's office, interrogated the

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registered nurse and served a second Notice of Inspection.

Plaintiff believes that she is being investigated concerning a drug called Liefcort. Although she claims that FDA lacks jurisdiction under the Act<sup>2</sup> to investigate or inspect either her practice or the treatment she prescribes for her patients, she asserts her willingness to discuss with FDA officials, through her attorney, details of medications which she prepares, prescribes and administers to her patients.

FDA acknowledges that its desire to inspect plaintiff's premises stems from a belief that in the course of plaintiff's practice she may be distributing Liefcort, a drug not approved by FDA. Liefcort, which is apparently used outside this country in the treatment of arthritis, is believed to consist of prednisone, testosterone and estradiol, in proportions known only to its discoverer, the late Dr. Robert Liefmann. FDA believes that some of it may have been shipped into the country and found its way into plaintiff's offices.

Essentially four grounds are relied on in support of FDA's motion to dismiss or for summary judgment: (1) there

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HON. EDWARD R. NEAHER

is no justiciable controversy before the court; (2) FDA, an agency of the United States, has not consented to the suit and therefore it is barred by the doctrine of sovereign immunity; (3) there is an adequate remedy at law; and (4) FDA does have the statutory authority to investigate plaintiff's offices.

The absence of a justiciable controversy is premised on a lack of ripeness, a question necessarily involving a discretionary determination as to whether a particular controversy is appropriate for judicial resolution. In situations, such as this, where a pre-enforcement attack is made on the validity of administrative action, the Court, in the drug trilogy cases Abbott Laboratories v. Gardner, 387 U.S. 136 (1967); Toilet Goods Ass'n v. Gardner, 387 U.S. 158 (1967); Gardner v. Toilet Goods Ass'n, 387 U.S. 167 (1967), has established guidelines for ascertaining the appropriateness of judicial intervention.

The test to be applied is twofold in nature and involves an evaluation of "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." Abbott, supra, 387 U.S. at

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HON. EDWARD R. NEAHER

149. The first part of the test, i.e., the fitness of the issues for resolution, itself consists of two parts -- whether the issues raised were purely legal in nature and whether the challenged agency action was final. Id.

In Abbott, supra, the plaintiffs had challenged the authority of the Secretary of Health, Education and Welfare to promulgate certain regulations, which had already been the subject of hearings and had been published in final form with immediate compliance expected. Applying the two-part test, the Court noted that the tendered issues were purely legal and the agency action was in every respect final, not tentative, and not the action of a subordinate official. Abbott Laboratories, supra, 387 U.S. at 151. Additionally, the challenged regulations would have "a direct effect on the day-to-day business of all prescription drug companies . . ." (387 U.S. at 152), and therefore withholding judicial consideration would necessitate considerable hardship. Under those circumstances, the Court departed from the otherwise settled rule that courts are to avoid "entangling themselves in abstract disagreements over administrative policies" and that administrative agencies are entitled to

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be free "from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." Abbott Laboratories, supra, 387 U.S. at 148-49.

In this case, the only action taken by FDA has been to cause two notices of inspection to be served and to question plaintiff's nurse. The notices merely recite various statutory provisions authorizing FDA inspections without specifying the purpose of the inspection or what FDA expects to find on the premises it seeks to enter.<sup>3</sup>

Applying the Abbott Laboratories test to these facts, the court is of opinion that discretion should not be exercised in favor of retaining jurisdiction. While the issue raised appears to be a purely legal one, i.e., the FDA's statutory authority to inspect a physician's office, there is here no final agency action whose legality the court may pass upon. Although FDA agents made two visits to plaintiff's office, no inspection was in fact conducted. The court is reluctant to anticipate what future action, if any, FDA may decide to take.

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In American Dietetics Co., Inc. v. Celebrezze, 317 F.2d 658 (2 Cir. 1963), the court affirmed the dismissal of an action brought to enjoin FDA inspectors from using concealed tape recorders during future inspections of a plaintiff's premises, saying:

"There is no ground in such a single past incident for declaratory relief against possible future inspections. There is no actual controversy now existing on which to found declaratory relief. . . . 'Especially where governmental action is involved, courts should not intervene unless the need for equitable relief is clear, not remote or speculative.' [Quoting from Eccles v. People's Bank of Lakewood Village, Cal., 333 U.S. 426, 431, 68 S.Ct. 641, 644, 92 L.Ed. 784.]" 317 F.2d at 660.

That language is apposite here.

This case is also distinguishable from Abbott and Gardner on the question of the hardship of withholding judicial consideration at this time. In those cases the challenged regulations required the plaintiffs to take positive action which would have had "a direct effect on the[ir] day-to-day business . . . ." Here, no action on plaintiffs part is required — the ball, so to speak, is in FDA's court.

If FDA decides to pursue the matter further, there

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are two courses of action available. First, if FDA desires to enforce its claimed right of inspection under §374, it will have to seek the court's aid under §332, which grants the district courts jurisdiction to enjoin violations of §331. Subdivision (f) of §331 prohibits "[t]he refusal to permit entry or inspection as authorized by §374 . . . ." If relief were granted under §332 the occupant (plaintiff here) would be enjoined from refusing entry to FDA inspectors. Cf. Brennan v. Buckeye Industries, Inc., 374 F. Supp. 1350 (S.D. Ga. 1974). In such a proceeding plaintiff would have the opportunity to explain to the court her reasons for denying entry to the FDA inspectors and the legal issue raised could then be properly decided. See, e.g., FTC v. Simeon Management Corporation, 1975 Trade Cases ¶60,223 (N.D. Cal. 1975).

Second, FDA could institute criminal proceedings against plaintiff under 21 U.S.C. §333(a),<sup>4</sup> in which event she could raise as a defense FDA's lack of authority to inspect her office. See, e.g., United States v. Thriftmart, Inc., 429 F.2d 1006 (9 Cir.), cert. denied, 400 U.S. 926 (1970).

Plaintiff urges that she should not be required to

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test the legality of FDA's right to inspect her office in a criminal proceeding, on pain of conviction should she lose. Her fear of prosecution, however, is not a sufficient predicate for this court to retain jurisdiction. Here, there is no indication that the government intends to prosecute plaintiff either for her past two refusals to permit entry or for any future refusals -- unlike the situation in Doe v. Bolton, 410 U.S. 179, 93 S.Ct. 739 (1973), where physicians challenged the constitutionality of a Georgia abortion statute under whose predecessors doctors were actually prosecuted. Cf. Laird v. Tatum, 408 U.S. 1, 13, 92 S.Ct. 2318, 2325 (1972),<sup>5</sup> and Socialist Workers Party v. Attorney General of the United States, 510 F.2d 253 (2 Cir. 1974).

Moreover, absent compelling circumstances, such as presented in the Doe case, there is no basis for a court to issue a judgment declaring in advance of a criminal prosecution that acts already committed, or even to be committed in the future, are or are not unlawful. Cf. Ewing v. Mytinger & Casselberry, 339 U.S. 594, 599 (1950).

Finally, in construing statutes providing criminal penalties for individuals who refuse to honor administrative

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summonses, the courts have held in parallel situations that good faith noncompliance is not subject to prosecution. See Reisman v. Caplin, 375 U.S. 440, 446-49 (1964) (good faith refusal to honor an internal revenue service summons would be a defense to a prosecution under 26 U.S.C. §7210).<sup>6</sup> Similarly, in Anheuser-Busch, Inc. v. Federal Trade Commission, 359 F.2d 487 (8 Cir. 1966) (Blackmun, J.), the court held that §10 of the Federal Trade Commission Act, 15 U.S.C. §50, which makes it an offense to refuse "to answer any lawful inquiry . . . if in [one's] power to do so, in obedience to the subpoena or lawful requirement of the Commission . . .", does not authorize criminal prosecution "where the challenge to the subpoena is in good faith." 359 F.2d at 490. See also Federal Power Commission v. Metropolitan Edison Co., 304 U.S. 375, 386-87 (1938).

The court concludes that a controversy sufficiently ripe for adjudication does not presently exist between the parties. Defendants' motion for summary judgment dismissing the complaint is therefore granted.<sup>7</sup>

SO ORDERED.

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The Clerk of the Court is directed to enter judgment dismissing the complaint.

/s/ EDWARD R. NEAHER  
U. S. D. J.

Dated: Brooklyn, New York  
October 2, 1975

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F O O T N O T E S

1  
"§374. Inspection—Right of agents to enter;  
scope of inspection; notice; prompt-  
ness; exclusions

"(a) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any . . . establishment in which . . . drugs . . . are manufactured, processed, packed, or held, for introduction into interstate commerce . . . and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such . . . establishment . . . and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any . . . establishment . . . in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. . . . The provisions of the second sentence of this subsection shall not apply to—

\* \* \* \* \*

"(2) practitioners licensed by law to prescribe or administer drugs and who manu-

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facture, prepare, propagate, compound,  
or process drugs solely for use in the  
course of their professional practice  
. . . ."

2 Plaintiff also claims that FDA's construction of §374 violates the Fourth Amendment under the reasoning of Colonnade Catering Corporation v. United States, 397 U.S. 72 (1970), and United States v. Biswell, 406 U.S. 311 (1972).

3 Nor is FDA required under §374 to set forth in its notice the reason underlying the inspection or what it expects to find; the section simply and unequivocally authorizes FDA to enter and inspect certain specified premises at reasonable times. See fn. 1.

4 Section 333(a) provides:

"Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1,000, or both."

5 In refusing to permit a suit under the First Amendment seeking declaratory and injunctive relief against surveillance being conducted by the Army, the Court noted:

"At the same time, however, these decisions have in no way eroded the 'established principle that to entitle a private individual to invoke the judicial power to determine the validity of executive or legislative action he must show that he has sustained, or is immediately in danger of sustaining, a direct injury as the result of that action . . . .' Ex parte Levitt, 302 U.S. 633, 634, 58 S.Ct. 1, 82 L.Ed. 493 (1937)."

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The Court went on to conclude that to allow the action to proceed

"would have the federal courts as virtually continuing monitors of the wisdom and soundness of Executive action; such a role is appropriate for the Congress acting through its committees and the 'power of the purse'; it is not the role of the judiciary, absent actual present or immediately threatened injury resulting from unlawful governmental action." 408 U.S. at 15, 92 S.Ct. at 2326.

6 Section 7210 provides:

"Any person who, being duly summoned to appear to testify, or to appear and produce books, records, memoranda, or other papers . . . neglects to appear or to produce such books, accounts, records, memoranda, or other papers, shall, upon conviction thereof, be fined not more than \$1,000, or imprisoned not more than 1 year, or both, together with costs of prosecution."

7 Accordingly, it is not necessary for the court either to wade through the murky waters of sovereign immunity or to decide whether the Reisman, supra, and Anheuser-Busch, supra, cases mandate a dismissal of the action for want of equity.

NOTICE OF APPEAL

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

-----X  
ELIZABETH DALEY, M.D.,

Plaintiff,

-against-

CASPAR W. WEINBERGER, Secretary  
of Health, Education and Welfare,  
ALEXANDER M. SCHMIDT, M.D,  
Commissioner of the Food and Drug  
Administration, CLIFFORD G. SHANE,  
Regional Director of the Food and  
Drug Administration, TERRY MUSSON,  
ALLEN R. HALPER, JOHN E. KLEMMER,  
and THOMAS D. GARDINE, Employees  
of the Food and Drug Administration,

Defendants.  
-----X

No. 75 C 306

NOTICE OF APPEAL

Notice is hereby given that ELIZABETH DALEY, M.D., plaintiff  
above named, appeals to the United States Court of Appeals for  
the Second Circuit from the final judgment of HON. EDWARD R. NEAHER,  
dismissing the complaint herein, entered in this action on October  
2, 1975.

Dated: New York, New York  
October 31, 1975

ROTHBLATT, ROTHBLATT, SEIJAS

& PESKIN

By: *Henry B. Rothblatt*

HENRY B. ROTHBLATT

Attorneys for Appellant  
232 West End Avenue  
New York, New York 10023  
(212) 787-7001

TO: HON. DAVID G. TRAGER  
United States Attorney  
Eastern District of New York  
Attorney for Appellees

STATE OF NEW YORK )  
COUNTY OF NEW YORK) ss.:

EDMUND P. MARINELLI, being duly sworn,  
deposes and says that deponent is not a party to the action,  
is over 18 years of age and resides at 1135 UNIVERSITY AVE.  
BRONX, N.Y.

That on the 17<sup>th</sup> day of FEBRUARY, 1976,  
deponent personally served the within APPENDIX

upon the attorneys designated below who represent the  
indicated parties in this action and at the addresses below  
stated which are those that have been designated by said  
attorneys for that purpose.

By leaving 1 true copy~~ies~~ of same with a duly  
authorized person at their designated office.

~~By depositing true copies of same enclosed  
in a postpaid properly addressed wrapper, in the post office  
or official depository under the exclusive care and custody  
of the United States post office department within the State  
of New York.~~

Names of attorneys served, together with the names  
of the clients represented and the attorneys' designated  
addresses.

DAVID G. TRAGER, ESQ.  
UNITED STATES ATTORNEY FOR THE EASTERN DISTRICT  
OF NEW YORK - ATTORNEY FOR DEFENDANTS, APPELLES  
BY CYRIL HYMAN, ESQ. ASSISTANT U.S. ATTORNEY  
225 CADMAN PLAZA EAST  
BROOKLYN, N.Y. 11201

Edmund P. Marinelli

Sworn to before me this

17<sup>th</sup> day of February, 1976

Michael DeSantis

MICHAEL DeSANTIS  
Notary Public, State of New York  
No. 03-0930903  
Qualified in Bronx County  
Commission Expires March 30, 1977